

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2026 P 1508-1
Program	Prior Authorization/Notification
Medication	Dawnzera™ (donidalorsen)*
P&T Approval Date	1/2026
Effective Date	4/1/2026

1. Background:

Dawnzera* is a prekallikrein directed antisense oligonucleotide indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 12 years of age and older.

2. Coverage Criteria^a:

A. Initial Authorization

1. **Dawnzera*** will be approved based on **all** of the following criteria:

a. Diagnosis of hereditary angioedema (HAE)

-AND-

b. For prophylaxis against HAE attacks

-AND-

c. Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Cinryze, Haegarda, Orladeyo, Takhzyro)

Authorization will be issued for 12 months.

B. Reauthorization

1. **Dawnzera*** will be approved based on **both** of the following criteria:

a. Documentation of positive clinical response to Dawnzera* therapy

-AND-

b. Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Andembry, Cinryze, Haegarda, Orladeyo, Takhzyro)

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

* Dawnzera is typically excluded from coverage. Coverage reviews may be in place if required by law or the benefit plan.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Dawnzera [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; September 2025.

Program	Prior Authorization/Notification – Dawnzera™ (donidalorsen)
Change Control	
1/2026	New program.